Filing Date: September 22, 2003

Title: CARDIAC RHYTHM MANAGEMENT SYSTEM WITH EXERCISE TEST INTERFACE

## REMARKS

This responds to the Office Action dated September 19, 2006. Claims 38 and 72 are amended. Claims 1-37 are canceled. No claims are added. As a result, claims 38-80 are now pending in this patent application.

Applicant respectfully submits that the amendments to the claims are fully supported by the specification, as originally filed, and no new matter has been added. Applicant hereby respectfully requests further examination and reconsideration of the application in view of the following remarks.

# Affirmation of Election

Restriction to one of the following claims was required:

- I. Claims 1-37, drawn to a method, classified in class 607, subclass 27.
- II. Claims 38-80, drawn to a system, classified in class 607, subclass 32.

As provisionally elected by Applicant's representative, **Timothy E. Bianchi**, on September 11, 2006, Applicant elects to prosecute the invention of Group II, claims 38-80. The claims of the non-elected invention, claims 1-37, are hereby canceled without prejudice or disclaimer. Applicant reserves the right to later file continuations or divisions having claims directed to the non-elected inventions.

#### Objection to the Claims

Claims 38 and 72 were objected to due to minor typographical errors. Applicant has amended the claims to overcome this objection.

### §112 Rejection of the Claims

Claim 54 was rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicant respectfully traverses this rejection.

The Office Action at page 3 contends that "the phrase 'an elevated value of the resting heart rate' is confusing." The Office Action at page 3 further contends that "[o]ne of ordinary skill in the art would deem a resting heart rate to be a given value. If that given value is elevated, it is no longer a resting heart rate; the person has to be doing something other than resting to

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cause the heart rate to elevate." Applicant respectfully disagrees. In fact, it possible to have an elevated resting heart rate without performing any activity or "doing something other than resting". For instance, an elevated resting heart rate may be triggered by such things as stress, anxiety, fever, smoking, alcohol, caffeine consumption, respiratory or other illnesses, hyperthyroidism, anemia, and the use of certain decongestants and cough medications. (See https://www.healthforums.com/library/1,1258,article~10865,00.html.) From at least the above examples, it should be evident that a person need not necessarily physically do anything to have an elevated resting heart rate. Therefore, Applicant respectfully submits that the Office Action's asserted reason for indefiniteness is without basis. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 54.

# §102 Rejection of the Claims

Claims 38-40, 42, 49-52, 55, 56, 62, 64, 65, 68, 71-74, 76, and 80 were rejected under 35 1. U.S.C. § 102(b) for anticipation by Dardik (U.S. Patent No. 5,163,439).

As an initial note, Dardik does not appear on the PTO-892 form attached to the Office Action. Applicant respectfully requests that the Examiner cite the Dardik reference in a future PTO-892 form.

Applicant has amended claims 38 and 72 to overcome this rejection. Support for the amendments to claims 38 and 72 can be found in the as-filed specification at, for instance, page 7, lines 16-29, and Fig. 4; and page 8, line 19 to page 9, line 3, and Fig. 5. Applicant cannot find in Dardik each and every element presently recited or incorporated in claims 38-40, 42, 49-52, 55, 56, 62, 64, 65, 68, 71-74, 76, and 80. For instance, with respect to claims 38 and 72, as amended, Applicant cannot find in Dardik a processor circuit, including at least one predetermined criteria to automatically identify a beginning and an end of an exercise episode of a patient. Applicant cannot find a processor circuit in Dardik that automatically identifies a beginning and an end of an exercise episode. Instead, it appears that the Dardik device uses an adjustable timer 17 to determine "[t]he duration of this conditioning session". (Dardik, col. 4, lines 45-47.) Nothing in Dardik appears to disclose, teach, or even suggest automatic identification of the exercise episode, including automatic identification of the beginning of the exercise episode, and automatic identification of the end of the exercise episode. Indeed, a

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patient using the Dardik device could be exercising before its timer 17 is activated and after its timer 17 is deactivated. Similarly, a patient using the Dardik device could begin exercising after its timer is activated and could cease exercising before its timer is deactivated. For at least this reason, Applicant respectfully submits that Dardik does not include each and every recitation of claims 38 and 72, and, therefore, the rejection of claims 38 and 72 is improper.

Additionally, dependent claims 39, 40, 42, 49-52, 55, 56, 62, 64, 65, 68, and 71 depend from independent claim 38 and dependent claims 73, 74, 76, and 80 depend from independent claim 72 and accordingly incorporate the features of claims 38 and 72, respectively. These dependent claims are accordingly believed to be patentable for the reasons stated herein. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

For at least these reasons, Applicant believes claims 38-40, 42, 49-52, 55, 56, 62, 64, 65, 68, 71-74, 76, and 80 to be patentable over Dardik. Accordingly, Applicant respectfully submits that the § 102(b) rejection of claims 38-40, 42, 49-52, 55, 56, 62, 64, 65, 68, 71-74, 76, and 80 is improper and requests withdrawal of this rejection.

2. Claims 38 and 72 were rejected under 35 U.S.C. § 102(b) for anticipation by Heikkilä (U.S. Patent No. 5,840,039). Applicant has amended claims 38 and 72 to overcome this rejection. As stated above, support for the amendments to claims 38 and 72 can be found in the as-filed specification at, for instance, page 7, lines 16-29, and Fig. 4; and page 8, line 19 to page 9, line 3, and Fig. 5.

Applicant cannot find in Heikkilä each and every element recited in claims 38 and 72. For instance, with respect to claims 38 and 72, as amended, Applicant cannot find in Heikkilä a processor circuit, including at least one predetermined criteria to automatically identify a beginning and an end of an exercise episode of a patient. Applicant cannot find a processor circuit in Heikkilä that automatically identifies a beginning and an end of an exercise episode. The Office Action at page 5 states that "Heikkilä discloses a processor circuit (Fig. 3), including at least one predetermined criteria to identify a exercise episode of a patient (column 3, lines 56-58; column 4, lines 1-8)". However, Applicant cannot find anywhere in Heikkilä a processor circuit that uses predetermined criteria to automatically identify a beginning and an end of an

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exercise episode of a patient, as is recited in claims 38 and 72. Instead, the cited portions of Heikkilä apparently relate to "means 30 [that] calculates the heartbeat rate variation data and indicates the heartbeat rate variation in the display element 40", Heikkilä at col. 3, lines 56-59, and measuring "the heartbeat rate of a person and the timing moment of at least one waveform of the ECG signal . . . during the training period", Heikkilä at col. 4, lines 5-8. Although measuring heartbeat rate during a training period is discussed in Heikkilä, Applicant can find no recitation that the Heikkilä device automatically identifies a beginning and an end of an exercise episode. For at least this reason, Applicant respectfully submits that that Heikkilä fails to include each and every element recited in claims 38 and 72, and, therefore, the rejection of claims 38 and 72 is improper.

For at least these reasons, Applicant believes claims 38 and 72 to be patentable over Heikkilä. Accordingly, Applicant respectfully submits that the § 102(b) rejection of claims 38 and 72 is improper and requests withdrawal of this rejection.

### §103 Rejection of the Claims

1. Claims 41 and 75 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Heikkilä as applied to claims 38 and 72 above, and in view of Alexander et al. (U.S. Patent No. 5,243,993). Applicant respectfully traverses this rejection.

Claim 41 depends from claim 38, and claim 75 depends from claim 72. As stated above, Applicant believes claims 38 and 72 are allowable over Heikkilä. Even assuming, for the sake of argument, that Heikkilä and Alexander et al. are properly combinable, Alexander et al. does not remedy at least the apparent deficiencies of Heikkilä described above. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

Therefore, based upon at least their dependence from one of claims 38 and 72, respectively, Applicant respectfully submits that claims 41 and 75 are allowable and request reconsideration and withdrawal of the rejection of claims 41 and 75.

## AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

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Claims 43 and 77 were rejected under 35 U.S.C. § 103(a) as being unpatentable over 2. Heikkilä as applied to claims 38, 62, and 72 above, and in view of Gamlyn et al. (U.S. Patent No. 5,749,367). Applicant respectfully traverses this rejection.

As an initial note, Applicant can find no application of the Heikkilä reference to claim 62 called out in the rejection on page 7 of the Office Action. Applicant has assumed that the inclusion of claim 62 in this rejection was merely a typographical error by the Examiner and has, therefore, ignored it. If this assumption is incorrect, Applicant respectfully requests clarification and further opportunity to respond.

Claim 43 depends from claim 38, and claim 77 depends from claim 72. For the reasons stated above, Applicant believes claims 38 and 72 are allowable over Heikkilä. Even assuming, for the sake of argument, that Heikkilä and Gamlyn et al. are properly combinable, Gamlyn et al. does not remedy at least the apparent deficiencies of Heikkilä as described above. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

Therefore, based upon at least their dependence from one of claims 38 and 72, respectively, Applicant respectfully submits that claims 43 and 77 are allowable and request reconsideration and withdrawal of the rejection of claims 43 and 77.

Claims 53, 54, 57-61, 66, 67, 69, and 70 were rejected under 35 U.S.C. § 103(a) as being 3. unpatentable over Heikkilä. Applicant respectfully traverses this rejection.

Each of claims 53, 54, 57-61, 66, 67, 69, and 70 depends from claim 38. As stated above, Applicant believes claim 38 is allowable over Heikkilä. Accordingly, based upon at least their dependence from claim 38, Applicant respectfully submits that claims 43 and 77 are allowable. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

Moreover, Applicant respectfully traverses this single reference rejection under 35 U.S.C. § 103 because not all of the elements recited in the claims are found in the cited reference. Because all elements recited in the claims are not found in the reference, Applicant assumes that the Examiner is taking Official Notice of the missing elements. Applicant respectfully timely objects to the taking of Official Notice with a single reference obviousness rejection. Pursuant to

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M.P.E.P. § 2144.03, Applicant respectfully traverses the assertion of Official Notice and requests that the Examiner cite one or more references in support of the positions taken with respect to each of claims 53, 54, 57-61, 66, 67, 69, and 70.

Therefore, for at least the reasons stated above, Applicant respectfully submits that claims 53, 54, 57-61, 66, 67, 69, and 70 are allowable and request reconsideration and withdrawal of the rejection of claims 53, 54, 57-61, 66, 67, 69, and 70.

### Allowable Subject Matter

Claims 44-48, 63, 78, and 79 were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Each of claims 44-48, 63, 78, and 79 depend, either directly or indirectly, from one of independent claims 38 and 72. For at least the reasons stated above, Applicant believes claims 38 and 72 are in condition for allowance. Therefore, Applicant respectfully submits that claims 44-48, 63, 78, and 79 are similarly in condition for allowance, based at least upon their dependence from one of claims 38 and 72. However, Applicant reserves the right to rewrite claims 44-48, 63, 78, and 79 in independent form during later examination of the present application or any subsequent patent applications claiming priority thereof.

#### AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

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### **CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

**DAVID TERNES** 

By his Representatives,

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Date <u>December 19, 2006</u>

Ву \_

Suneel Arora Reg. No. 42,267

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this day of

December, 2006.

Name

**Signature**